Therapeutix
Product Manual
Therapeutix

Before operation, please read this user's manual carefully, and be clear about the instructions!

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I. Foreword

Before operation, please read this user's manual carefully, and be clear about the instructions.

Two key points for operations:

1) Locate the exact location of the pain: Apply the pads (electrodes) to the muscle area where you are experiencing pain, stiffness or soreness.

2) Intensity: The intensity should be gradually increased until you reach the highest setting before it becomes uncomfortable.

Structure and Accessories:

Included in this package:

* 1 controller
* 2 output electrode cables
* 1 charger
* 1 plastic holder
* 2 pairs of electrodes [510(k) cleared]
* 1 USB cable
* 1 User's manual

II. User manual

1. Warnings

1) The long-term effects of chronic electrical stimulation are unknown.
2) Do not use stimulation over the main arteries around your neck.
3) Do not use stimulation over the neck or mouth. Severe spasm of muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing.
4) Do not apply stimulation directly to the heart area across the chest or on the chest.
5) Do not use stimulation on your head or across your head.
6) Do not use stimulation over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis,varicose veins.
7) Do not use stimulation over, or in proximity to, cancerous lesions.
8) Do not use stimulation when charging the device.

2. Precautions

1) Do not use the muscle stimulator during pregnancy.
2) Do not use if you have heart problems.
3) Do not use if you have epilepsy.
4) Do not use the device in the presence of the following:
a. When there is a tendency to hemorrhage following acute trauma or fracture;
b. Following recent surgical procedures when muscle contraction may disrupt the healing process;
c. Over the menstruating or pregnant uterus;
d. Over areas of the skin which lack normal sensation.

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5) Do not use the products near the heart, it may cause fast or irregular heartbeat.
6) Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using an alternate conductive medium (like gel), or alternate electrode placement.
7) Therapeutix TENS&PMS must be kept out of the reach of children.
8) Therapeutix TENS&PMS should be used only with the leads and electrodes recommended for use by the manufacturer.
9) Never apply the pads to your skin with the power on, which will result in sudden shock. If, during application, you want to move the pads to another body part, please shut down the device first, and then move the pads to the place that you want to stimulate.
10) Never use this product near the following devices: pacemakers or any other embedded electronic medical devices, heart-lung machine and any other life keeping electronic medical devices, electrocardiograph and any other medical screening and monitoring devices. Simultaneous use of the Therapeutix TENS&PMS and any of the above devices will cause malfunction and can be very dangerous to the users.
11) Two pads should be used together as a pair. Always peel off the protective film on the pads before use. To avoid an electrical short, do not connect two pads to each other.
12) Do not apply pads to the same spot for over 60 minutes at a time.
13) Do not use the Therapeutix TENS&PMS while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user at undue risk of injury.
14) Do not use the product in bathroom or a moist environment. Do not use while bathing.
15) Do not use the product in the condition of air mixed with flammable gases.
16) Never use this product in concurrence with high frequency surgical equipment; it may result in burns at the site of the stimulator electrodes and possible damage to the control unit.

17) Never use this product near a microwave oven, or other high frequency equipment.
18) Never use this product while it is being charged.
19) Do not operate the product in close proximity (e.g. 1m/3ft)) to shortwave therapy equipment, it may produce instability in stimulator output.

3. Contraindication
1) Do not use this device on patients who have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device, because this may cause electric shock, burns, electrical interference, or death.
2) Do not use this device on patients whose pain syndromes are undiagnosed.
3) Do not use this device during pregnancy.
4) Do not use this device on babies or infants who cannot express themselves.

4. Adverse Reactions
1) Patients may experience skin irritation and burns beneath the stimulation electrodes applied to the skin;
2) Patients may experience headache and other painful sensations during or following the application of electrical stimulation.
3) Patients should stop using the device and should consult with their physicians if they experience adverse reactions from the device.

5. Indications for Use
TENS:
To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities. Choose Mode 1, 3, 4, 5, 6.
PMS:
It is intended to be used to stimulate healthy muscles in order to improve and

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facilitate muscle performance. Choose Mode 1, 2, 3, 6.

6. Description of the Device

6.1 General Description of the Device

Therapeutix TENS & PMS is a portable and DC 3.7V battery powered multifunction device, offering both Transcutaneous Electrical Nerve Stimulation (TENS) and Powered Muscle Stimulation (PMS) qualities in one device.
Therapeutix TENS & PMS has 6 operation modes, which can give certain electrical pulses through electrode adhesive pads to the suggested area of the body where the electrodes are placed.
The electronic stimulatory module has the operating elements of an ON/OFF Switch, Display screen, Mode Selection key, Intensity Modification keys, Timing key, Pause key, Output socket, and USB port for battery charging.
The display screen can show battery power, selected mode, current intensity, time remaining of an application mode, and indication of a pause (Page 10, No. 10).
The device is equipped with accessories of electrode pads, electrode cables, a battery charger, and one USB cable. The electrode cables are used to connect the pads to the device; the USB cable is used to connect the charger and the built-in lithium battery. All accessories, including USB cables, electrode pads, electrode cables, chargers can only be changed or replaced by a qualified person.
The electrodes are interchangeable. The application area of electrode pads must be larger than the smaller electrode pads. The electrode pads are provided by GMDASZ Manufacturing Co., Ltd. with 510(k) cleared Number K092546.

6.2 Specifications and Essential performance:

(Essential performance: The values of pulse duration, amplitudes, and repetition frequencies do not deviate by more than ±30% when measured with an error not exceeding ±10% into a load resistance (500Ω) within the range specified by the manufacturer.)

- Power supply: DC 3.7V
- Output voltage: 42V@500Ω
- Output current: 84mA@500Ω
- Consumed current: 40mA
- Pulse width: 100μS
- Frequency: 1~110Hz
- Smallest are of electrode pad: 4cm2
- Timer: 10~60 minutes
- Strength level adjustment: 20 grades
- Charger: Input: 100-240V 50/60Hz 0.18A Max; Output: DC5V 250mA; Class II, not applied part, not suitable for use in the presence of a flammable gases, with oxygen or nitrous oxide, or for continuous operation..

6.3 Features

* A large, easy to read LCD display
* Adjustable timer
* 6 Modes
* Rechargeable lithium battery

6.4 Mode Description

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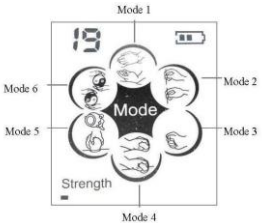
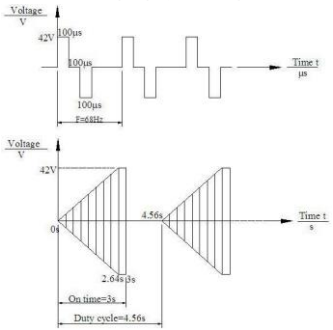
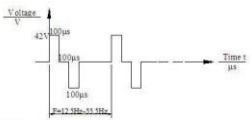


We suggested that you initially experiment using each of the 6 modes. The mode that gives you the most desirable sensations and comfort is the most appropriate one to use for your current condition.

1) Intensity should be set at a level where you will feel some muscular vibration and involuntary muscle movements.
It should be set to give a comfortable feeling and should not be painful.
2) Timing of application should be at least 10 to 20 minutes.
3) Frequency of the application should be at least one to three times per day.

Modes	Parameters	Graphical Description
Mode 1	1) Timing: 10~60 minutes 2) Frequency: 68Hz 3) Pulse width: 100μS 4) On time: 3s 5) Off time: 1.56s 6) Duty cycle: 4.56s	The amplitude for the whole pulse takes 2.64 seconds from zero to maximum and stays on for 0.36 seconds; then the device stops for 1.56 seconds. The device repeats this cycle all the time. The output frequency is 68Hz and the pulse width is 100μS. 
Mode 2	1) Timing: 10~60 minutes 2) Frequency: 12.5~55.5Hz 3) Pulse width: 100μS 4) On time: 20.S 5) Off time: 1s 6) Duty cycle: 21s	The output amplitude and pulse width (100μS) are fixed; the frequency changes among 12.5Hz to 55.5Hz; and there are 64 periods (on 220ms, off 100ms), then the device stops for 1 second. The device repeats this cycle all the time. 

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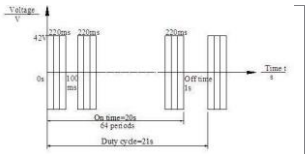
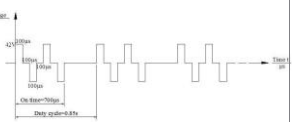
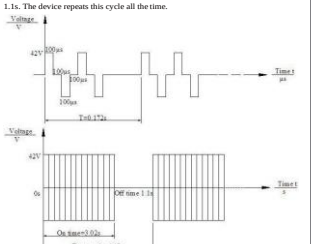
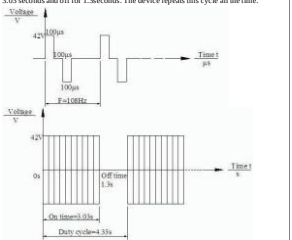
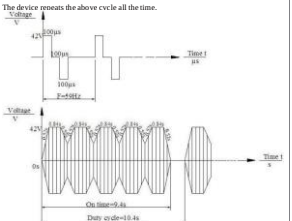
		
Mode 3	1) Timing: 10~60 minutes 2) Pulse train frequency: 1.17Hz 3) Pulse width: 100μS 4) On time: 0.7ms 5) Off time: 849.3ms 6) Duty cycle: 850ms	The device outputs 2 groups of symmetrical pulse at intervals of 0.85 seconds. The pulse width is 100μS fixed. 
Mode 4	1) Timing: 10~60 minutes 2) Pulse train frequency: 5.813Hz 3) Pulse width: 100μS 4) On time: 3.02s 5) Off time: 1.1s 6) Duty cycle: 4.12s	The device outputs 2 groups of symmetrical pulse at intervals of 0.172s. The pulse width is 100μS fixed. The whole waveform works for 3.02s and stops for 1.1s. The device repeats this cycle all the time. 

Mode 5	1) Timing: 10~60 minutes 2) Frequency: 108.2 Hz 3) Pulse width: 100μS 4) On time: 3.03s 5) Off time: 1.3s 6) Duty cycle: 4.33s	The output frequency (108Hz), amplitude and pulse width (100μS) are fixed, on for 3.03 seconds and off for 1.3seconds. The device repeats this cycle all the time. 
Mode 6	1) Timing: 10~60 minutes 2) Frequency: 59Hz 3) Pulse width: 100μS 4) Build-up phase: 0.52s 5) Working time: 0.84s 6) Run-down phase: 0.52s 7) Pause phase: 1s 8) Duty cycle: 10.4s	The output frequency (59Hz) and pulse width (100μS) do not change; the amplitude for the whole pulse takes 0.52s from zero to maximum and stays for 0.84s; then it takes 0.52s from maximum to a half. Then the device repeats 3 times of the following: the amplitude for the whole pulse takes 0.52s from a half to maximum and lasts for 0.84s; then it takes 0.52s from maximum to ahalf. Then the amplitude for the whole pulse takes 0.52s from a half to maximum and lasts for 0.84s; then it takes 0.52s from maximum to 0, and stops for 1s. The device reneats the above cvcle all the time. 

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7. Direction for Use

7.1 General Operation Guidance

1) The Therapeutix TENS & PMS unit needs to be charged for up to 10 hours before the first use.

2) Connect the electrode cables to the output sockets at the bottom of the unit.

3) Connect the pads to the cables by snapping them on.

4) Use a damp towel to wipe the skin where you intend to put the pads, so as to remove any body oil, cosmetic or dirt. Remove the protective film and place the pads on the area making sure that both pads are on the skin and not overlapping.

Warning: To avoid an electrical short, never put two electrode pads together.

5) Turn on the unit by sliding the On/Off switch from Off to On.

Warning: Do not move pads or touch them with your hands during use, it may cause strong stimulation.

6) When you have turned on the unit, the LCD display will automatically show Mode 1. The "T" (Timer) will automatically choose the time duration of 20 minutes.

7) To change the modes, press the M (Mode) button. Once you have selected a mode, gradually increase the intensity by pressing the + button, and to decrease the intensity by pressing the – button. The chosen power output depends on your comfort level. At the precondition of acceptance, the intensity should be chosen as high as possible for the best effect but still feelcomfortable.

8) To set the time of use, press the T button. The auto time set is 20 minutes. Each press of the T button increases the time by 10 minutes. After the time runs out the device turns off automatically, and it can be restarted if treatment is needed to be continued.

9) Sit back and enjoy the deep soothing sensations!

Notes: The Therapeutix TENS & PMS unit is very safe, the output intensity increases only by pushing the + key. Even if the intensity is increased to the maximum, it is within the safe range, but may feel uncomfortable. When the user switches the mode, the intensity will automatically go down to the minimum for safety reasons.

10) Press the Pause key ("►II" button) to lock the LCD display, the "MODE" display

will blink.The device will not work no matter what key you press on the control panel,it is locked.To unlock press the Pause key again.
11) If you need to turn off the device during stimulation, slide the On/Off switch to "OFF".
12) Before storing the TENS & PMS use the protective film to cover the electrode pads.
Notes:
① Never connects this product with a common headphone.
② Please do not touch the USB port when using the device. The USB port is only used to connect the charger, do not connect other devices.
③ The charger supplied by the manufacturer must in compliance with IEC/EN 60601-1, the use of unauthorized chargers can impair the safety.
④ The battery needs to be charged for up to 10 hours before the first use.

7.2 Electrode guidelines
1) Use only the electrodes supplied by the manufacturer; other electrodes may present a risk of unsuitable electrical characteristics with your stimulator.
2) Do not use the electrodes on different people, otherwise, skin reaction or cross contamination may occur.
3) Always turn power off before removing or repositioning the electrodes.
4) Wash skin thoroughly, and then dry it before applying the electrodes.
5) Apply the whole surface of the electrodes firmly to the skin. Do not use electrodes that do not stick properly to the skin or only partially stick to the skin.
6) In case of skin redness under the electrodes after a stimulation session, do not start a new session in the same place if skin redness is still evident.

7.3 Regular TENS Application principles
1) Find the exact pain point or the area where the muscles ache most. For best relief of pain, place the electrode pair from one channel on either side of the pain. (See Figure 1: Twin mode) or you may place one electrode on the painful site and

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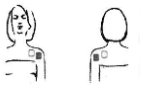
the other near the site of pain.
2) Intensity: The intensity can be gradually increased up to the point when it becomes uncomfortable. Always stay below that point of discomfort.
3) Recommended application duration and Mode selection:
When starting out, choose Mode 1 at a low Intensity level for 10 minutes up to 3 times a day. You may increase the intensity and time after you have become familiar with the device and the feel for the stimulation. Stay with Mode 1 for a few days before trying any of the other Modes and intensity settings. Remember, the modes to be used for pain relief are Modes 1, 2,3, 4, 5 and 6.
It is difficult to recommend a particular mode for a specific type of pain and it is usually determined by the user's feel of relief.
However, if you do not feel any relief of pain after having tried different modes and intensities it is recommended that you consult with your physician.
4) If the stimulation sensation becomes weaker or disappears, you may increase the intensity by pressing the up key (+) to a point when the stimulation becomes uncomfortable, but if the sensation does become uncomfortable, press the down key (-) to decrease the intensity. Always stay under the point of discomfort!
5) If you experience an adverse reaction (skin irritation/redness/burns /other painful sensation), or if you feel unusual discomfort, stop using the device immediately.
6) There are two ways to place the pads, in twin or opposed modes.

Fix the two pads from one channel on either side of the pain area, or one electrode on the painful site and the other near the site of pain, but on the same side of body. If you want to use both channels at the same time, make sure that the second pair of electrodes is also fixed near the side of pain on the same side of the body (right under or over the first pair)

Figure 1: Twin mode (this is the correct mode)

Fixing the two or four pads respectively on the opposite sides of the body is not recommended and provides little benefit.

Figure 2: Opposed mode (Not recommended)



7.4 Regular TENS Application Methods

Use the device for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities.

Users can choose Mode 1, 2, 3, 4, 5 or 6 for temporary relief of pain.

* Many people experience immediate relief from muscle pain, while others require several days of regular use to feel the benefits. The results vary and will depend upon your underlying conditions and how often you use the device.

If your pain does not improve, you can try to increase the intensity and time or change the mode.

Note:

The charts below are merely a suggestion for where to place the electrodes, what Mode to choose and how long to stimulate, but only after the user has gone through the starting procedure (above) and is familiar with the device.

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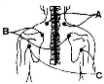
• Pain in Neck	Figure 3: 	Mode 1 (A) for 10-20 minutes, and Mode 3 for 10-20 minutes; twice or 3 times a day. * Keep the neck warm and avoid sleeping on a high pillow.
• Pain in shoulders		Mode 4 (B & C) for 10-20 minutes, and Mode 5 for 10-20 minutes; twice or 3 times a day. * Find the pain area and apply the electrodes at the anterior and posterior (inner & outer) shoulders. * Keep the area warm. Avoid sudden movements with the aching shoulders, gentle movements are advisable in the initial stage and full motions at a later stage.
• Pain in Back		Mode 1 for 10-20 minutes, and Mode 5 or 6 for 10-20 minutes; twice or 3 times a day. * Apply the electrodes to the pain area. * Avoid working in the same position in the initial phase and change the position at times.
• Pain in Waist	Figure 4:	Mode 3 or 6 to stimulate (A) for 10-20 minutes, Mode 1 to stimulate (B and C) for 10-20 minutes; twice or 3 times a day.
• Pain in Joints and limbs	Figure 5:	Mode 1 for 10-20 minutes, and Mode 4 for 10-20 minutes; twice or 3 times a day.
	Figure 6:	Mode 3 for 10-20 minutes, and Mode 4 for 10-20 minutes; twice or 3 times a day.
	Figure 7:	Mode 1 for 20 minutes and Mode 3 for 20 minutes; twice or 3 times a day.
	Figure 8:	Mode 4 for 10-20 minutes, and Mode 6 for 10-20 minutes; twice or 3 times a day. * Do not use this device directly on the pain area or area of injury.

7.5 Regular PMS Application principles

1) Identify the targeted muscle which needs to be stimulated. In order to improve or facilitate muscle performance, place the two electrodes from one channel on opposite ends of the muscle or close to the belly of the muscle. (See Figure 9)
If you like to work with both channels at the same time you may place the second electrode pair near the first pair or onto another muscle to be stimulated like the biceps on the opposite arm in Fig 9 below.

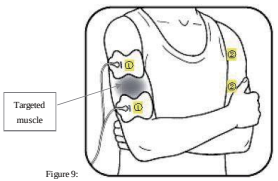


Figure 9:

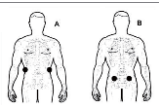
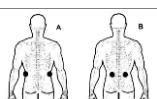
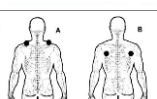
2) Intensity: The intensity can be gradually increased up to the point when it becomes uncomfortable. Always stay below that point of discomfort.
3) Recommended application duration and Mode selection:
The modes to be used for improving the muscle performance are Modes 1, 2, 3 and 6.
Mode 1: exercise preparation
Mode 2: Build endurance
Mode 6: muscle strengthening
Mode 3: Active recovery

7.6 Regular PMS Application Methods

This function is intended to stimulate healthy muscles including abdomen muscles in order to improve or facilitate muscle performance.
You can use the electrode adhesive pads on almost every muscle and joint area on your body. Please note that this device is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. It is not intended as therapy for any medical condition.
Users can choose Mode 1, 2, 3 or 6 to stimulate the following points to quickly facilitate muscle performance. In order to better improve the muscle performance, you may increase the intensity gradually to a level which is still comfortable and does not cause pain or discomfort. Furthermore, you should use the Therapeutix TENS & PMS regularly to maintain the benefit you may have gained during exercise.

Note:

The charts below are merely a suggestion for how to place the electrodes, what Mode to choose and how long to stimulate, only after the user has gone through the starting procedure (above) and is familiar with the device.

• Abdomen		Mode 1 for 10-20 minutes, Mode 2 for 10-20 minutes, and Mode 6 for 10-20 minutes; twice or 3 times a day. * Persistent and consistent use can help to improve the abdomen muscles.
• Waist		Mode 1 for 10-20 minutes, Mode 3 for 10-20 minutes, and Mode 6 for 10-20 minutes; twice or 3 times a day. The device exercises the muscles in the waist * It is advisable to do some waist exercise after the application.
• Shoulders and Back		Mode 1 for 10-20 minutes, and Mode 2 or 3 for 10-20 minutes; twice or 3 times a day. Apply the electrodes to the points shown to exercise these shoulder muscles

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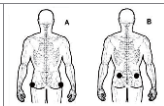
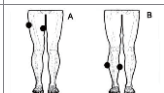
• Buttocks		Mode 1 for 10-20 minutes, and Mode 6 for 10-20 minutes; twice or 3 times a day. Apply the device to the points shown to exercise the muscles.
• Legs		Mode 1 for 10-20 minutes, Mode 2 for 10-20 minutes, and Mode 3 for 10-20 minutes; twice or 3 times a day. The device can stimulate areas of the legs and thighs so as to improve the muscles.

8. Battery

8.1 Battery information

Capacity: 110mAh

Voltage: DC 3.7V

Restriction: 4.2V

8.2 Charging the Battery

1) The Lithium battery can be recharged through both AC adaptor and computer USB input.

2) Turn off the unit.

3) Connect the unit and the charger with USB extension cord. Plug charger into any power outlet, a green light shows that it is charging. The charging process will last approximately 1 hour. When charging is finished, the LCD will show a full battery cell.

4) The battery should be charged for 10 hours or so before first use. We have done this for you!

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Notes: Only charge the unit when battery is completely drained the first 2 times. Unplug the charger from power outlet when charging is complete. When stimulation intensity decreases, it indicates that the device needs charging. Recharge it and then continue to use the device. Do not use the device while charging.

9. Readjustments, alterations and repairs

1) Do not disassemble, repair or modify the device without authorization, you will void any warranty on the product.

2) The manufacturer is only responsible for the safety and performance of Therapeutix TENS & PMS when readjustments, alterations and repairs are carried out by authorized individuals and when the Therapeutix TENS & PMS is used in accordance with the user instructions.

3) Qualified technicians who are familiar with the technical features of the device have been provided with circuit diagrams, PCB drawings, component lists and setting instructions by the manufacturer.

10. Cleaning and maintenance

A. For the control unit:

1) To keep the controller clean, use a soft and dry cloth for dust or a soft damp cloth for any dirt and smudges. Do not use any cleaning solutions to clean the controller and its pads.

2) Do not use or store the device where there are magnetic fields or electric waves (near TV set or speakers).

3) Do not place the devices in areas of high temperature, high humidity, or under direct sunlight.

4) Keep the device out of reach of children.

5) All worn accessories should be disposed of according to your local regulations.

B. For electrode pads:

* Refer to the user manual of the pads manufacturer (510K092546), or reference to the following suggestions:
1) Unplug the output cord from the output jack of the controller after each use. Cover both pads with the protective film before storage. Never fold the electrode pads.
2) Between uses, store the electrodes in the reusable bag in a shady place. Stockroom temperature: +5°C~+27°C (41-80°F) and humidity of 30%~80%. No need to sterilize.
3) Never apply the pads to any other surface other than your skin. If the pads become soiled or dirty, the adhesive power may decrease. In this case, moisten the surface of the pads with water and wipe away the dirty portion. This will allow a temporary restoration of the adhesive power. However, too much water will result in loss of the adhesive power.
4) The life of the electrodes varies depending on skin conditions, storage, amount of use, type of stimulation, and stimulation site. Electrode life may be extended by carefully following this Instruction for Use. The expired electrodes are to be recycled and do not harm environment.
Warning: The electrodes are intended for single patient use only!

11. Storage
Caution: Do not store in a damp area. Dampness may affect the device and cause rust.
- Normal working ambient temperature: 5°C~40°C (40-104°F)
- Normal working ambient humidity: ≤80%RH
- Store and transport ambient temperature: -20°C~55°C (4° -131° F)
- Store and transport ambient humidity: ≤93%RH

12. Technical checks
Technical checks on the device should be performed every 24 months.
These include:

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1. Checking to see whether the user instructions and the medical device book are included in the accompanying documentation.
2. Checking the equipment for completeness.
3. Visual check:
- for mechanical damage
- for damage to all cables and connections
4. Functional safety
- Checking the output signals with a load resistance of 500Ω real (current and voltage)
- Checking the frequency
- Checking the pulse width.
These technical checks may only be performed by individuals with appropriate training. The results must be noted in the medical device book along with the date and name of the person carrying out the check.

13. Troubleshooting

Problems		Possible causes	Try this solution
No.	One pad feels stronger than the other.	This is normal. Different areas of your body will react differently.	Nothing needs to be done. Make sure the pads are sticky and are making good contact.
1	The intensity is not felt. Very weak intensity level.	Pads are not attached to the body firmly.	Attach both pads firmly to the skin.
		The transparent films are still stuck to the pads.	Peel off film on the adhesive surface of pads.
		The pads stacked together or overlap.	Do not stack pads together or overlap pads.
		The cord is not properly connected to the unit.	Connect cord correctly into the jack.
		The intensity setting is getting weak.	Increase the intensity level.
		The battery capacity is low.	Charge the battery.
2	The skin turns red or the skin feels irritated.	The adhesive surface of pads is dirty or dry.	Wash adhesive surface of pads softly with your fingertips for about 3 seconds under slow running water.
		The therapy time is too long or the intensity is set too high.	Reduce the application time or reduce the intensity.
		The electrode pad surface is worn out.	Replace electrode pad.
3	No power source; no display in LCD.	The battery capacity is depleted.	Charge the battery.
4	Power cut off during use.	The battery is weak.	Charge the battery.
		The cord is broken.	Replace the cord.
5	It is difficult to attach the pad to the skin.	Have you removed the transparent film from the pad?	Peel off film on the adhesive surface of pads.
		Was the pad applied immediately after washing?	Dry the pad.
		Is the adhesive surface of the pad damaged?	Replace the pad.
6	Adhesive surface of pad is not sticky.	Are you using pad when perspiring?	Use when not perspiring, in a cool room.
		Were the pads stored under high temperature, high humidity, or direct sunshine?	Replace the pad.

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14. Disposal of the Unit

To dispose of the unit, its accessories and packing materials, take appropriate actions in accordance with the rules and regulations in force in your area to prevent adverse ecological effects.

15. Warranty period

We give a lifetime warranty from the date of purchase on Therapeutix TENS & PMS. This warranty does not cover cables and electrodes.

16. Electromagnetic Compatibility

Important information regarding Electro Magnetic Compatibility (EMC)
With the increased number of electronic devices such as PC and mobile (cellular) telephones, radio transceivers, mobile radio transmitters, radio-controlled toys, and so on, Medical devices in use may be susceptible to electromagnetic interference from other device. Electromagnetic interference may result in incorrect operation of the medical devices and create a potentially unsafe situation. Medical devices should also not interfere with other devices.

In order to regulate the requirements for EMC (Electro Magnetic Compatibility) with the aim to prevent unsafe product situations, the EN60601-1-2 standard has been implemented. This standard defines the levels of immunity to electromagnetic interference as well as maximum levels of electromagnetic emissions for medical devices.

This unit has been thoroughly tested and inspected to assure proper performance and operation! This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided,
the following tables recommend minimum separation distances between portable and mobile RF communications equipment and the TENS unit.

Caution:

* The use of accessories and cables other than those specified by Therapeutix, with the exception of cables sold by Therapeutix as replacement parts for internal components, may result in increased emission or decreased immunity of the device.
* Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit. This may result in incorrect operation of the unit.
* This device should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this device should be observed to verify normal operation in the configuration in which it will be used.
* Refer to further guidance below regarding the EMC environment in which the device should be used.

There is no guarantee that interference will not occur in a particular installation. Radiated or conducted electromagnetic signals can cause:

1) As to devices:

• Deviation of the values of pulse duration, amplitudes, and repetition frequencies, may impair the unit's essential performance. The device has passed EMC highest interference level test, and the parameters do not deviate the essential performance requirement.
• The device displays abnormally in LCD.

2) As to patients:

• The sensitivity of stimulation may be weaker or stronger, but it does not produce safety issues.
• It cannot achieve expected effect.

If this equipment is found to cause or respond to interference, attempt to correct the problem by one or more of the following measures:

• If feeling too weak or too strong stimulation, adjust the strength level to an acceptable level.
• If the device display is abnormal, power off and restart the device and check whether it shows properly.

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• Re-orient or re-locate the affected device.
• Increase the separation between the unit and the affected device.
• Power the equipment from a source other than that of the affected device.
• Consult the service representative for further suggestions.

1) Guidance and manufacture's declaration – electromagnetic emission

The Therapeutix TENS & PMS is intended for use in the electromagnetic environment specified below. The customer of the user of the Therapeutix TENS & PMS should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The Therapeutix TENS & PMS uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	The Therapeutix TENS & PMS is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC61000-3-3	Complies	

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2) Guidance and manufacture's declaration – electromagnetic immunity

The Therapeutix TENS & PMS is intended for use in the electromagnetic environment specified below. The customer or the user of Therapeutix TENS & PMS should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s)	±1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Therapeutix TENS & PMS requires continued operation during power mains interruptions, it is recommended that the Therapeutix TENS & PMS be powered from an uninterruptible power supply or a battery.
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE UT is the a.c. mains voltage prior to application of the test level.

3) Guidance and manufacture's declaration – electromagnetic immunity

The Therapeutix TENS & PMS is intended for use in the electromagnetic environment specified below. The customer or the user of Therapeutix TENS & PMS should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Therapeutix TENS & PMS, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.167\sqrt{P}$ $d = 1.167\sqrt{P}$ 80 MHz to 800 MHz $d = 2.333\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz-2.5 GHz	3 V/m	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Therapeutix TENS & PMS is used exceeds the applicable RF compliance level above, the Therapeutix TENS & PMS should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Therapeutix TENS & PMS. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

4) Recommended separation distances between portable and mobile RF communications equipment and the Therapeutix TENS & PMS

The Therapeutix TENS & PMS is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Therapeutix TENS & PMS can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Therapeutix TENS & PMS as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 KHz to 80 MHz $d = 1.167\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.167\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.333\sqrt{P}$
0.01	**0.117**	**0.117**	**0.233**
0.1	**0.369**	**0.369**	**0.738**
1	**1.167**	**1.167**	**2.333**
10	**3.689**	**3.689**	**7.379**
100	**11.667**	**11.667**	**23.333**

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

17. Date

Issue date of the manual: 12-25-2014	Production date: 12-30-2014	Batch: xxx-xxx

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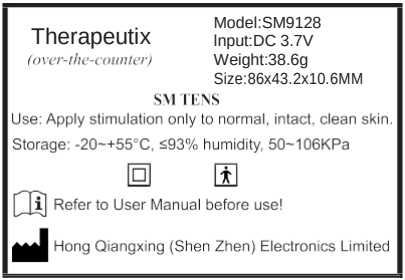
III. Labels on the device



Notes:

Symbol	**Meaning**
	Class II equipment
	Type BF applied part
	Operating instructions
	Manufacturer